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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,188	04/14/1998	DOMINIC P. BEHAN	AREN-001CIP(001.US2.CIP)	9333

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
09/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/060,188	BEHAN ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,45-52,61,62,69,77,79 and 81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,45-52,61,62,69,77,79 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 6/26/09 has been entered in full. Claims 34, 45, 52, 69, 77 and 79 are amended. Claim 80 is canceled (claims 1-33, 35-44, 53-60, 63-68, 70-76 and 78 are canceled). New claim 81 is added.

Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are under consideration.

Elections/Restrictions

A review of the complete record of the application indicates that the pending claims do not include any subject matter drawn to either non-elected inventions (as set forth in the Restriction Requirement mailed 6/24/1999) or non-elected species (as set forth in the Restriction Requirements mailed on 6/19/2001 and 7/2/2002). Therefore, the restriction requirements set forth previously are currently moot, and each restriction requirement is herewith withdrawn. It is noted that said restriction requirements will be reinstated if the non-elected subject matter is re-introduced into the pending claims.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (4/9/08).

All rejections of claim 80 are moot in view of Applicants' cancellation of the claim.

The rejection of claims 34, 45, 48, 61, 77 and 79 under 35 U.S.C. § 102(b) at pg 10-12 as anticipated by Eggerickx et al, 1995 is *withdrawn* in view of Applicants' amendments to independent claim 77, from which each of the other claims depends. Claim 77 has been amended to require that the constitutively activated GPCR comprises a mutation that increases its constitutive activity relative to the endogenous orphan GPCR (i.e., the unmutated version). The constitutive activity of the ACCA receptor described by Eggerickx et al is not due to a mutation in the receptor; therefore the teachings of Eggerickx et al do not anticipate the claims as amended.

Maintained Objections and/or Rejections

Claim Rejections - 35 USC § 101, utility

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection was set forth previously and maintained at pg 3-9 of the 4/9/08 Office Action for claims 34, 45-52, 61, 62, 69, 77 and 79; new claim 81 is herewith included in this rejection.

The rejection is first restated in view of Applicants' amendments to the claims, and then Applicants' arguments are addressed.

Independent claim 69 has been amended to remove the statement from the preamble reciting "wherein said endogenous GPCR comprises a mutation in its amino acid sequence so as to render it constitutively" and add a new method step reciting "(a) obtaining a constitutively activated form of said endogenous GPCR, wherein said constitutively activated GPCR comprises a mutation in its amino acid sequence that increases its constitutive activity relative to said endogenous GPCR", and to change the verb of step (c) from "determining" to "analyzing". Independent claim 77 has been amended to add/alter method step (a) to one identical to that for claim 69, to change the verb of step (c) from "determining" to "analyzing", and to delete the words "orphan" and "endogenous" from steps (b) and (d). New claim 81 has been added which depends from claim 81 and limits the method to one performed in a laboratory or research setting. These amendments have been fully considered, but are not sufficient to overcome the rejection for lack of utility set forth previously and reiterated herein.

As set forth in MPEP 2107, a ""specific utility" is *specific* to the subject matter claimed and can "provide a well-defined and particular benefit to the public" [citing *In re Fisher*]…This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personal should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations

where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating specified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound (citing *In re Kirk* and *In re Joly*)…Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition". Furthermore, MPEP 2017 states, "Thus, a "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities…the following are examples of situations that require or constitute carrying out further research to identify or confirm a "real world" context of use and, therefore, do not define "substantial utilities": A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved. B. A method of treating an *unspecified* disease or condition. C. A method of assaying for or identifying a material that itself has no "specific and/or substantial utility"…" (pg 6).

In the case *In re Fisher* (76 USPQ2d 1225 (CA FC 2005)) the U.S. Court of Appeals Federal Circuit stated, "Patent application does not satisfy utility requirement of 35 U.S.C. §101 unless it discloses both "substantial" utility for claimed invention, in form of significant and presently available benefit to public, as well as "specific" utility, which is well-defined and particular benefit to public" (pg 1225) and "an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public" (pg 1230).

In the instant case, the claimed methods lack a specific and substantial utility because there is no specific and substantial utility for a non-endogenous compound modulatory compound identified by the claimed methods. Each orphan GPCR described in the specification for use with the claimed method lacks a specific and substantial utility. Furthermore, identification of a non-endogenous compound that can stimulate (i.e., agonize) or inhibit (i.e., antagonize) the activity of an orphan receptor

does not provide a specific and substantial utility for such an identified compound. The specification teaches that such compounds may prove useful without identifying a specific use for the stimulation or inhibition of particular orphan GPCRs. The specification does not provide a reasonable correlation between the activity of any of the orphan GPCRs and a specific and substantial use (e.g., treatment of a disease associated with the activity of the GPCR).

Previously (see the 6/13/07 Office Action; pg 8), it was considered that the specification describes that the expression of GPR3, an orphan GPCR, is associated with epilepsy. The specification teaches, "GPR3 is expressed in much higher levels in human epilepsy tissue samples (tissue source: temporal cortex), as compared with controls, as evidenced by RT-PCR analysis (Figure 15)" (pg 75). However, the association of GPR3 with a specific disease (epilepsy) does not provide a specific and substantial utility for the claimed method even as practiced with GPR3. While measurement of increased GPR3 expression could possibly be used to confirm a diagnosis of epilepsy, this finding does not provide a use for agonists or antagonists of GPR3 identified by the claimed methods. The overexpression of GPCR in tissue from a person with a particular disease does not reasonably indicate that increased activity of said GPCR is a cause of the disease rather than a consequence. For example, with respect GPCR perturbations in the disease hypertension, "it has been difficult to determine whether they are the cause or consequence of the disease" (Feldman, 2002. Molecular Pharmacology. 61(4): 707-709; cited previously). With respect to temporal lobe epilepsy, Janigro (2008. Epilepsy Currents 8(1): 23-24; cited previously) teaches that "[a]s with many pathological findings in neurodegenerative diseases, it is difficult to determine if the changes are a cause or consequence of epileptic seizures" (pg 23). As such, at the time of filing it would require further research for the skilled artisan to confirm that increased GPR3 activity plays a role in epilepsy, such that administration of an antagonist could be used to treat epilepsy. Thus, it would require further research for the skilled artisan to identify or confirm a “real world” context of use for the agonists and antagonists of GPR3 identified by the claimed methods. Furthermore, it appears that GPR3 is no longer encompassed by the instant claims, as it is an endogenously

constitutively active GPCR and the claims require a GPCR that has been constitutively activated by mutation.

In summary, the proposed uses of the claimed invention to identify non-endogenous compounds that modulate the activity of orphan GPCRs requires further research to identify a specific and substantial use for the identified compound. Therefore, the application fails to provide guidance as to how one of skill in the art could use the claimed method in a way that constitutes a specific and substantial utility.

Applicants' arguments (twice filed; 10/9/08, pg 6-10 and 6/26/09, pg 6-10) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

At pg 7, Applicants argue that the statement in MPEP 2107 that reads "(C) A method for assaying for or identifying a material that itself has no specific and/or substantial utility" is being applied to the subject invention. Applicants argue that an "assaying for or identifying a material" are "those assays which merely detect the presence or absence of an analyte in a sample" and the claimed invention is not drawn to such an assay. Applicants argue that an "assaying for or identifying a material" "does not contemplate screening assays that analyze the functional activity of a compound". Applicants argue a distinction between screening a plurality of compounds to find compounds that can modulate a particular orphan GPCR and an assay that merely assays for or identifies a material in a sample.

Applicants' arguments have been fully considered but are not found persuasive. The quoted part "(C)" of MPEP 2107 was not exclusively applied to the instant rejection over the totality of the statements of MPEP 2107. The quoted part "(C)" of MPEP 2107 is merely one non-limiting example of a situation that requires or constitutes carrying out further research to identify or confirm a "real world" context of use. As quoted previously and herein (see above), MPEP 2017 states, "Thus, a "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities…**the following are examples** of situations that require or constitute carrying out further

research to identify or confirm a “real world” context of use and, therefore, do not define “substantial utilities”: A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved. B. A method of treating an *unspecified* disease or condition. C. A method of assaying for or identifying a material that itself has no “specific and/or substantial utility”…” (pg 6, **emphasis** added by Examiner). Thus, any distinction present between the claimed method and the method recited in "C" is not of itself sufficient to impart a substantial utility to the claimed invention. For the reasons set forth previously and reiterated herein (see above), the claimed method lacks a specific and substantial utility.

At pg 7, Applicants further argue that a different section of MPEP 2107 is applicable to the instant invention, specifically 2107.01(C), heading "Research Tools". Applicants argue that this section states that "research tools that are used in a research or laboratory setting .. have "a clear, specific and unquestionable utility" and that instant invention is such a research tool. At pg 8, Applicants argue that the utility "is clearly described throughout the specification as providing researchers in the field with a novel approach to by-pass the significant bottle-neck in the orphan GPCR field, i.e., waiting for an orphan GPCR to be "de-orphanized" prior to conducting further functional studies".

Applicants’ arguments have been fully considered but are not found persuasive. Applicant's arguments include statements taken from Section "C. Research Tools" of MPEP 2107 but do not address other statements founds in this section. Specifically, this section also states that "[a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as “research tool,” “intermediate” or “for research purposes” are not helpful in determining if an applicant has identified a specific and substantial utility for the invention". As set forth in the above rejection, in the instant case further research would be required to identify a specific and substantial use for modulating compounds

identified by the claimed method. Therefore, the claimed method lacks a specific and substantial utility. Thus, Applicants' arguments that the instant invention has utility solely because it is a "Research Tool" are not persuasive. Furthermore, the argument that the instant invention can "by-pass the significant bottle-neck in the orphan GPCR filed" by de-orphanizing a receptor is merely a restatement of the argument that the claimed invention is a "research tool" and does not provide a specific and substantial utility for the claimed invention at the time of filing. Furthermore, any benefits of "by-passing a bottleneck" with regard to expense, time or success of identifying non-endogenous modulating compounds of orphan receptors does not obviate the requirement for a specific and substantial use for the compounds once identified.

At pg 8, Applicants argue that the skilled artisan would not screen an orphan GPCR if there was not some use for the identified compounds. Applicants further argue that the specific reasons for screening will vary but are based on the activity of a GPCR in a specific cellular process such as a disease such as viral entry or an expression pattern of particular interest such as in a specific diseased tissue or in cells at a specific developmental stage. Applicants argue that the claimed method has utility in allowing the user to identify specific modulatory compounds from a library of candidates. At pages 7 and 9, Applicants argue that the claimed methods identify compounds that "can be employed in a predictable manner as reagents that have a known effect on the orphan GPCR (i.e., as agonists of inverse agonists)" (pg 7) and that the identified compounds have as much immediate utility as would the endogenous ligand for the receptor because they can be employed in "a predictable manner as reagents that have a known effect on the orphan GPCR (e.g., as agonists or inverse agonists)" and thus no further experiments are required for the claimed screening method to have utility (pg 9).

Applicants' arguments have been fully considered but are not found persuasive. Applicants' argument that the "skilled artisan" will provide "some use" for the identified compounds does not provide an immediate, real-world utility for the claimed method of screening at the time of filing of the instant application. The disclosure of an orphan GPCR with a specific cellular process in the instant specification could possibly provide a specific and substantial utility for the claimed invention; however, it is maintained that

the instant application at the time of filing does not identify any such GPCRs. It is maintained that identification of modulatory compounds from a group of candidate compounds does not provide an immediate, real-world utility for the method of screening in absence of an immediate real-world use for said modulatory compound once identified. The fact that said modulatory compounds can be employed in a predictable manner to modulate the orphan receptor does not provide an immediate, real-world utility for said modulation; said modulation would be performed predictably for no purpose other than further research.

At pg 8, Applicants further argue that "as with sequencing assays, or, as argued previously, PCR assays, the user of the claimed screening assay determines which specific entity is the subject of the analysis (i.e., which specific orphan GPCR is to be employed to identify modulatory compounds)" (pg 8).

Applicants' arguments have been fully considered but are not found persuasive. With respect to "sequencing assays" and "PCR assays", Applicants do not identify a specific granted patent with claims which are analogous to the instant claims. DNA sequencing and PCR were developed long before the publication of the revised Utility Examination Guidelines 1/5/01 in the Federal Register. It is noted that at the time of invention of PCR in 1983, many nucleic acid sequences existed that either had utility as markers or to encode specific proteins with utility. Thus, at the time of invention, PCR had immediate utility in producing large quantities of identical copies of nucleic acids with specific and substantial utility. In contrast, the instantly claimed methods are limited solely to identifying non-endogenous modulators of "orphan GPCRs" (i.e., a GPCR for which an endogenous ligand has not been identified). There is no specific and substantial utility for any of the non-endogenous compounds identified by the claimed methods. Further research would be required to identify a use for any of the modulators identified by the claimed methods. Applicants' claimed methods are analogous to a gene chip in which none of the genes on the chip is a characterized gene. In general, gene chips are commercially successful and the skilled artisan would believe them to be useful. However, a gene chip would not meet the utility requirement if none of the genes on the chip had a specific and substantial utility.

At pg 8, Applicants argue that prior to the filing date of the present application "orphan GPCRs having a specific function or activity had been identified, and that modulatory compounds for such an orphan GPCR do indeed have specific and substantial utility". Applicants point to references (previously submitted with the response filed on 11/13/07) "which disclose orphan receptor STRL33, gpr1 and gpr15 as co-factors for retroviral entry into cells" (pg 8-9). Applicants argue that "it is a common misperception that orphan receptors, and by extension compounds that modulate orphan receptors, have no utility", that knowledge of a natural ligand is not needed for establishing a useful function for a receptor, and that a receptor's function can be known and targeting agents developed without any understanding of the natural ligand which activates it. Applicants argue that many opiates "were identified and developed and the analgesic functionality of these compounds at the mu-opiate receptor was appreciated long before the first endogenous agonists of that receptor were discovered in 1975" (pg 9, referencing Zadina et al, 1995 submitted as Exhibit B).

Applicants' arguments have been fully considered but are not found persuasive. The known function of STRL33, gpr1 and gpr15 as co-factors for retroviral entry into cells does not provide a specific and substantial utility of the modulators identified by the claimed method. The co-factors bind a complex of retrovirus and CD40 and mediate entry of the factor, whereas the instant claims are directed to method of screening for modulators of the constitutive activity of the receptors. The instant specification does not establish any correspondence between the use of modulators of the claimed invention and the role of STRL33, gpr1 and gpr15 in retroviral co-entry. For instance, it is not clear how such modulators would be used in relation to retroviral co-entry. Furthermore, these receptors are not disclosed in the instant specification, and use of modulators in blocking retroviral entry is not taught as a utility for modulators of the instant invention. Determining if such a correspondence exists would constitute carrying out further research to identify or reasonably confirm a "real world" context of use.

Furthermore, STRL33, gpr1 and gpr15 are not receptors encompassed by the claims at the time of filing. Claims 69 and 70 recite that "an endogenous ligand for said endogenous GPCR has not been identified". The specification defines the term

"endogenous" as "shall mean a material which a mammal naturally produces" (pg 18, line 22) and "ligand" as "shall mean an endogenous, naturally occurring molecule specific for an endogenous, naturally occurring receptor" (pg 22, lines 4-5). The previously submitted references provide evidence of identification of an endogenous, naturally occurring molecule specific for each of STRL33, gpr1, and gpr15. Farzan et al (1998; Exhibit B) teaches that "The gp120 [viral] glycoprotein binds the CD4 molecule, following which the gp120-CD4 complex binds one of the members of the chemokine receptor subgroup of seven-transmembrane segment (7-TMS) receptor" (pg 405). Farzan et al further identifies the 7-TMS receptors gpr1 and gpr15 as "coreceptors for SIV [simian immunodeficiency virus]". Thus, Farzan et al teaches that the gp120-CD4 complex binds to each of gpr1 and gpr15. Farzan et al does not teach whether or not the CD4 portion of the complex binds directly to gpr1 or gpr15, but the term "specific" encompasses either direct or indirect binding through a second molecule (i.e., the gp120-CD4 complex "specifically" binds to gpr1 or gpr15 as opposed to binding to most other cell surface molecules). The CD4 component of this complex is a material which a mammal naturally produces, and thus meets the definition of endogenous in the instant specification. Thus, Farzan et al teach an endogenous, naturally occurring molecule (CD4) specific for gpr1 and gpr15. Thus, Farzan et al teach an endogenous ligand (CD4) for gpr1 and gpr15. Thus, gpr1 and gpr15 are not receptors as defined by the instant claims. Similarly, Liao et al (1997; Exhibit B) teaches that STRL33 is a cofactor for HIV entry in cells expressing CD4; thus CD4 is an endogenous ligand for STRL33. In conclusion, at the time of filing of the instant application neither of STRL33, gpr1 or gpr15 was a receptor as encompassed by the instant claims.

As stated by Applicants, an endogenous agonist for the mu-opiate receptor was identified in 1975. Thus, the mu-opiate receptor does not provide support for the claimed invention because at the time of filing of the instant application it was not an orphan receptor and thus is not encompassed by the claimed invention. Furthermore, the various mammalian mu-opiate receptors were not cloned until the early 1990s. Thus, mutated versions of the receptors could not have been made until well after the endogenous ligand for receptor was identified. Thus, the status of the receptor prior to

1975 as an orphan receptor for which a non-endogenous ligand was identified is not germane to the claimed invention, as the claimed invention could not be practiced with said receptor.

At page 10, Applicants make several comments on the response to an argument made previously. In the 1/30/08 response, Applicants argued (pg 7) that U.S. Patent 5,462,856 (Exhibit A with the 1/30/08 response) provides an "example from the GPCR screening field of patented claims that are not limited to a particular GPCR". In the 4/9/08 Office Action, this argument was responded to as follows. Applicants' arguments have been fully considered but are not found persuasive. The claims in the '856 patent are not limited to a method of screening with an "orphan GPCR", but instead are directed to a method of screening for an agonist or antagonist of any "GPC receptor" (GPCR). At the time of invention, there existed a number of GPCRs with specific and substantial utility that could be used in the claimed method and thus provided the claimed method with immediate real-world utility. For example, in working examples 1-5 taught by the '856 patent (col 15-17), the method of screening is used to identify agonists and/or antagonists of the beta 2-adrenergic receptor (Examples 1 and 2), α2 adrenergic receptor (Examples 3 and 4) or the serotonin receptor (Examples 5). The ligand and activity of each of these GPCRs was known. In contrast, the claimed method is not directed to GPCRs in general, but is instead limited to orphan GPCRs that have no known ligand and which have no known activity that can be modulated for a useful purpose. Furthermore, it is noted that the '856 patent issued on 10/31/05 [sic, for 10/31/95], which is prior to the publication of the revised Utility Examination Guidelines 1/5/01 in the Federal Register.

At page 10 of the current response, Applicants first submit that "in contrast to the assertion in the Office Action, orphan GPCRs have been identified that have a known activity, e.g., the mu-opiate receptor". Applicants further note that "the '856 patent was issued after publication of the revised Utility Examination Guidelines of 1/5/01 (the '856 patent issued on 10/31/05)".

Applicants' arguments have been fully considered but are not found persuasive. Applicants' arguments regarding the mu-opiate receptor are addressed above.

Furthermore, the previous Office Action contained a typographical error regarding the publication of U.S. Patent 5,462,856. According to USPTO records, U.S. Patent 5,462,856 was published on October 31, 1995, and not on October 31, 2005. Therefore, it is maintained that the '856 patent issued prior to the publication of the revised Utility Examination Guidelines 1/5/01 in the Federal Register.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. This rejection was set forth previously and maintained at pg 9 of the 4/9/08 Office Action for claims 34, 45-52, 61, 62, 69, 77 and 79; new claim 81 is herewith included in this rejection.

Applicants' arguments (twice filed; 10/9/08, pg 10 and 6/26/09, pg 10) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In each response, Applicants submit that the rejection of the claims for lack of utility "has been adequately addressed in the discussion in the preceding section of this response" (i.e., Applicants' response to the rejection under 35 U.S.C. § 101).

Applicants' arguments have been fully considered but are not found persuasive. For the reasons described above in the section "Claim Rejections – 35 USC § 101", the claimed invention is not supported by a specific and substantial asserted utility, and therefore it is maintained that one of skill would not know how to use the claimed invention without undue experimentation.

Conclusion

No claims are allowed.

Applicants' amendment necessitated the new grounds of rejection presented in this Office action. Specifically, Applicants' amendments to the claims to add new claim 81 necessitated the rejection of this claim under 35 USC § 101 and 102.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647